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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,100	11/21/2001	Takashi Fujita	01626C/HG	2878

1933 7590 01/10/2003

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EXAMINER
STOCKTON, LAURA LYNNE

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 01/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	10

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on November 7, 2002.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~or thirty days~~, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-9 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-9 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING 3 PAGES--

09/901,177

DETAILED ACTION

Claims 1-9 are pending in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite because the claim does not state the disease/disorder which is being treated.

Response to Amendment

The Declaration under 37 CFR 1.132 filed November 7, 2002 is insufficient to overcome the rejection of claims 1-9 over Fujita et al. {U.S. Pat. 5,886,014} based upon a 35 U.S.C. § 103 rejection as set

forth in the last Office action because: (1) the Declaration is not executed; (2) the showing is not unexpected because one skilled in the art would expect that the salt form of a compound would be more soluble than the base form thereby increasing bioavailability and activity; and (3) the Declaration states Compound 3 (page 2) but shows data for Compound B (page 4). It is not clear if Compound 3 is in fact Compound B.

As stated in the previous Office Action, the showing in the instant specification on pages 7 and 8 has been considered. Berge et al. on page 1, column 1, states, "The chemical, biological, physical and economic characteristics of medicinal agents can be manipulated and, hence, often optimized by conversion to a salt form." Berge et al. also teach that the hydrochloride salt is a FDA approved salt and the mono-protic hydrochlorides have been the most frequent choice of the available anionic salt-forming radicals (page 2, columns 1 and 2). Berge et al. further teach that, "The salt form is known to influence a number of physicochemical properties of the parent compound including dissolution

rate, solubility, stability and hygroscopicity" (page 5, column 1).

Therefore, the showing is not persuasive because the result is not unexpected.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23, 25, 30 and 32-116 of U.S. Patent No. 5,886,014. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims of the patent differ only by generic description.

See, especially, the compound of claim 25 in '014 which differs from the instant claims in that a specific pharmaceutically acceptable salt is not claimed. One skilled in the art would thus be motivated to prepare a pharmaceutically acceptable salt of a known compound (e.g. hydrochloride salt) to arrive at the instant claimed product with the expectation of increasing solubility and hygroscopicity of the known parent (or base) compound. Therefore, the instant claimed invention would have been suggested to one skilled in the art.

Claim 3 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

claims 1-12, 14 and 22 of copending Application No. 10/053,136 (U.S. Patent Application Publication 2002/0137776). Although the conflicting claims are not identical, they are not patentably distinct from each other because of the generic description of the product used in the method claims of 10/053,136. See Example 1 in 10/053,136 (or see page 4, paragraph [0068] in the U.S. 2002/0137776). This is the same compound listed in instant claim 1 in which the method of use of claim 3 depends. One skilled in the art would thus be motivated to utilize the product disclosed in 10/053,136 with the expectation of treating cancer. Therefore, the claimed invention would have been suggested to one skilled in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Fujita et al. {U.S. Pat. 5,886,014}.

Fujita et al. disclose the parent (or base) compound, that pharmaceutically acceptable salts are preferred, especially the hydrohalic acids, such as hydrochloric acid (compound I-49 in column 29; column 22, lines 23-25, 36 and 37; and column 160, lines 1-37). Therefore, Fujita et al. anticipate the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujita et al. {U.S. Pat. 5,886,014}, especially in view of the teaching in Berge et al. {Journal of Pharmaceutical Sciences (January 1977), Volume 66, No. 1, pages 1-19}.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim the hydrochloride salt of a thiazolidin-2,4-dione compound. Fujita et al. teach a hydrochloride salt of a thiazolidin-2,4-dione compound (column 29, compound I-49; column 24, line 30; and column 22, lines 23-25, 36 and 37; and column 160, lines 1-37).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference, if any, is the selection of the particular pharmaceutically acceptable salt.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The selection of the hydrochloride salt of a known compound is *prima facie* obvious. Fujita et al. teach that pharmaceutically acceptable salts are preferred (column 22, lines 36-37). Fujita et al. also teach that the hydrohalic acids, such as hydrochloric acid, are preferred (column 22, lines 23-25). Berge et al. teach that the hydrochloride salt is a FDA approved salt and the mono-protic hydrochlorides have been the most frequent choice of the available anionic salt-forming radicals (page 2, columns 1 and 2). Berge et al. further teach that, "The salt form is known to influence a number of physicochemical properties of the parent compound including dissolution rate, solubility, stability and hygroscopicity" (page 5, column 1).

One skilled in the art would thus be motivated to prepare the hydrochloride salt of a known compound to arrive at the instant claimed

invention with the expectation of improving properties of the parent (or base) compound such as solubility and hygroscopicity. Therefore, the instant claimed invention would have been suggested to one skilled in the art.

Response to Arguments

Applicants' arguments filed November 7, 2002 have been fully considered. Applicants argue that: (1) although the instant claimed hydrochloride salt is within the broad scope of Fujita et al. {U.S. Pat. 5,886,014}, the reference does not anticipate the instant claims; and (2) the hydrochloride salt of the present claims shows a much greater effect of improving biological activity.

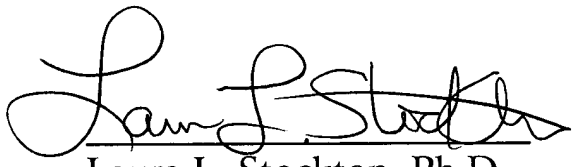
All of Applicants' arguments have been considered but have not been found persuasive. Applicants claim the hydrochloride salt of a thiazolidin-2,4-dione compound Fujita et al. disclose the parent (or base) compound, that pharmaceutically acceptable salts are preferred, especially the hydrohalic acids, such as hydrochloric acid (compound I-49

in column 29; column 22, lines 23-25, 36 and 37; and column 160, lines 1-37). Further, the showing found in the unexecuted Declaration has been discussed above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (703) 308-1875. The examiner can normally be reached on Monday-Friday from 6:00 am to 2:30 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.



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January 8, 2003